Practical Implementation of Nursing Science

Use of Closed System Transfer Devices in Oncology Clinical Trials: Establishing Processes and Overcoming Challenges

PUBLISHED ABSTRACT

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Significance: National guidelines on the safe handling and administration of hazardous drugs requires the use of Closed System Transfer Devices (CSTDs) to minimize risk of occupational exposure and promote patient, staff, and environmental safety. CSTDs are drug transfer devices that reduce hazardous drug exposure and are standard practice at the Mount Sinai Hospital, a 1,139-bed teaching hospital in New York City. The institution's policy is to treat all investigational products as hazardous until established safety data indicates otherwise. Safety data for early phase clinical trials remains largely inconclusive, yet sponsors often deem investigational products as non-hazardous based on a theoretical low risk of exposure, thereby disallowing use of CSTDs. Paucity of data regarding material compatibility, numerous CSTD brands, and the time and resources needed to conduct compatibility testing indicate that a standard process is needed for handling investigational products when CSTDs are not permitted by the sponsor.

Purpose: The goal was to develop a standard operating procedure (SOP) for handling investigational products when CSTDs are not permitted by the sponsor.

Methods: A review of national recommendations and guidelines confirmed that all antineoplastic investigational products should be handled as hazardous. Correspondence with academic institutions nationwide regarding similar challenges further cemented the need to develop an SOP. First, CSTDs used at the institution were expanded from two to four brands. After a review of the literature, an SOP compliant with institutional and United States Pharmacopeia standards was developed by nurses and pharmacists. The SOP, "Safe Handling of Investigational Antineoplastic products where use of Closed System Transfer Devices (CSTDs) are not permitted," included a research pathway for when CSTDs are not allowed.

1. Sponsors are required to provide clinical data along with a written statement that the investigational product is non-hazardous.
2. Concurrently, a structured four-step questionnaire, "Hazardous Evaluation of Investigational Antineoplastics Products" (Hazardous Evaluation Form) adapted from the American Society of Health System Pharmacists is completed by the research pharmacist.
3. If the investigational product is deemed hazardous, a multi-disciplinary team (physicians, leaders from the Clinical Research Support Unit, pharmacists, and nurses) determines whether it is safe to proceed with the study.

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4. If deemed non-hazardous, the study can proceed; compatibility testing with institutionally approved CSTDs is strongly recommended. Sponsors must notify the site as new data emerges regarding the hazardous profile of the investigational product.

Findings: Four studies were executed using the newly developed SOP. Of the four studies, one sponsor agreed to utilize one of the institutionally approved CSTD options. In two studies, the investigational product was deemed non-hazardous after completion of the Hazardous Evaluation Form and waived the use of CSTDs. The last study was deemed hazardous per the Hazardous Evaluation Form and confirmed by the multi-disciplinary team. The sponsor found a compatible CSTD and the study was ultimately initiated.

Conclusion: The SOP was effective in initiating clinical trials with potentially hazardous antineoplastic investigational products without compromising the safety of staff. The institution also recognized the importance of initiating timely discussions with the sponsor at study start-up. A similar process can be adopted where collaboration with key stakeholders proves vital to resolve other challenges encountered with early phase clinical trials.

COMPETING INTERESTS

The authors have no competing interests to declare.

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